To: Palich, Christian[palich.christian@epa.gov]
Cc: Beck, Nancy[Beck.Nancy@epa.gov]; Baptist, Erik[baptist.erik@epa.gov]; Lyons, Troy[lyons.troy@epa.gov]; Fugh, Justina[Fugh.Justina@epa.gov]
From: Dourson, Michael (doursoml)
Sent: Tue 9/5/2017 3:24:01 PM
Subject: Re: Response to Senator Carper
image001.jpg
Question 3-Project Database January 2010 to June 2015.xls

Christian

Here is the attachment for question 3. I am having some difficulty sending the attachment for question 6, since this is a series of presentations. I may have to send this attachment in groups. The responses to questions 10-12 still need the magic pen of Counselor Fugh.

Cheers!

Michael

-- Keep Calm and *ITER*ate! (http://www.tera.org/peer/ITERReview)

Risk Science Center
Department of Environmental Health

From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Tuesday, September 5, 2017 at 8:02 AM
To: "Palich, Christian" <palich.christian@epa.gov>
Cc: "Beck, Nancy" <Beck.Nancy@epa.gov>, "Baptist, Erik" <baptist.erik@epa.gov>, "Lyons, Troy" <lyons.troy@epa.gov>, "fugh.justina@epa.gov" <fugh.justina@epa.gov>
Subject: Re: Response to Senator Carper

Christian

Here are the attachments for question 9.

Cheers!

Michael

— Risk Science Center (formerly TERA Center) sponsors the International Toxicity Estimates for Risk (ITER) database of risk assessment values on Toxnet: http://toxnet.nlm.nih.gov/

Risk Science Center
Department of Environmental Health

From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Monday, September 4, 2017 at 8:42 PM
To: "Palich, Christian" <palich.christian@epa.gov>
Cc: "Beck, Nancy" <Beck.Nancy@epa.gov>, "Baptist, Erik" <baptist.erik@epa.gov>, "Lyons, Troy" <lyons.troy@epa.gov>, "fugh.justina@epa.gov" <fugh.justina@epa.gov>
Subject: Response to Senator Carper

Christian

Please find attached my response to Senator Carper. This set includes a slightly revised letter and responses to individual questions. Attachments for questions 1, 2, 6, and 9 will come in separate emails. The attachment for question 3 is still under development.

Of course, all of this is draft and comments are welcome.

Cheers!

Michael

-- *If you can't explain it simply, you don't understand it well enough. Albert Einstein*

Risk Science Center
Department of Environmental Health

From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Sunday, September 3, 2017 at 4:22 PM
To: "Palich, Christian" <palich.christian@epa.gov>
Subject: Re: Opening Statement of Michael Dourson

Christian

Please find attached my letter to Senator Carper to be sent with my responses to his questions. I would be happy to take comments on it.

Cheers!

Michael

—The right to search for the truth implies also a duty; one must not conceal any part of what one has recognized to be true. Albert Einstein.

From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Friday, September 1, 2017 at 3:19 PM
To: "Palich, Christian" <palich.christian@epa.gov>
Subject: Re: Opening Statement of Michael Dourson

Christian

This will not be a problem. Have a nice weekend.

Michael

-- *Risk Science Center (formerly TERA Center)*
Integrating assessments for both human and environmental health. See
http://www.tera.org/EcoTERA/index.html

From: "Palich, Christian" <palich.christian@epa.gov>
Date: Friday, September 1, 2017 at 12:57 PM
To: Michael Dourson <doursoml@ucmail.uc.edu>
Cc: "Fugh, Justina" <Fugh.Justina@epa.gov>, "Lyons, Troy" <lyons.troy@epa.gov>, "Shimmin, Kaitlyn" <shimmin.kaitlyn@epa.gov>
Subject: RE: Opening Statement of Michael Dourson

Thanks Dr. Dourson,

If you could please provide the supporting documents for these questions by Tuesday September 5th that would be great so we can quickly turn this around to Ranking Member Carper by the 6th.

Have a great weekend,

Christian R. Palich

Deputy Associate Administrator

Office of Congressional & Intergovernmental Affairs

U.S Environmental Protection Agency

O: 202.564.4944

C: Ex. 6 - Personal Privacy

E: Palich.Christian@epa.gov

From: Dourson, Michael (doursoml) [mailto:doursoml@ucmail.uc.edu]
Sent: Friday, September 1, 2017 10:35 AM
To: Palich, Christian <palich.christian@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>
Subject: Opening Statement of Michael Dourson

Christian

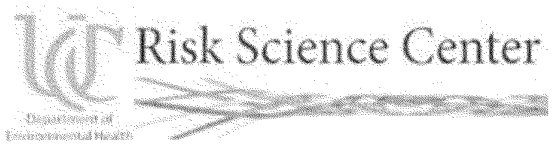
Here is a revised opening statement, and also a draft of my response to Senator Carper. I am still working on the attachments to this draft response and will send you a more complete draft response next week with attachments. This attachment is just to give you a sense of where I am heading. Also, Justina Fugh will be drafting what are likely much more appropriate answers for questions 10, 11 and 12.

Comments welcome.

Cheers!

Michael

-- If you can't explain it simply, you don't understand it well enough. Albert Einstein


Risk Science Center
Department of Environmental Health

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AWWA - American Water Works Association
Battelle Memorial Institute
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Battelle Memorial Institute
Bowles and Verna LLP
British Society of Toxicology
California Chamber of Commerce
Cardno Chemrisk
CEFIC
Charles A. Pittinger, LLC
Chevron
Chevron Phillips Chemical LP
Chevron Phillips Chemical LP
City of Cincinnati
Combined Federal Campaign
Coca Cola
Concurrent Technologies Corporation
Corona Environmental Consulting, LLC
Dow AgroSciences
Dow Chemical

Dow Chemical
Dow Chemical
Dow Corning
Dow Corning
Drinker, Biddle & Reath LLP
Eastern Research Group
Electric Power Research Institute
Eli Lilly
EnRisks
EnSIGHT
ERM Alaska, Inc.
Ethyleneamines Product Stewardship Discussion Group
ExxonMobil Biomedical Sciences, Inc
Genentech
Georgia Pacific
GMA
Gradient
Gradient
Halogenated Solvents Industry Alliance
Hamp, Mathews & Associates, Inc.
HAP Task Force
Health Canada
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ICL-IP America Inc.
ILSI North America
Institute of Environmental Science & Research Limited
Institute of Environmental Science & Research Limited
Institute of Environmental Science & Research Limited
Institute of Environmental Science & Research Limited
Institute of Environmental Science & Research Limited
Institute of Environmental Science & Research Limited
JT International S.A.
LifeLine Group
LifeLine Group
LifeLine Group
Lockheed Martin
Longenecker & Associates
McKenna Long and Aldridge
Merck & Co.
Merck & Co.
Methanol Institute
Morrison & Foerster
Multiple sponsors
Multiple sponsors
Nease Corporation
Neptune
New Zealand Ministry of Health
New Zealand Ministry of Health
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NSF International
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NSF International
NSF International
Ohio State University
Ontario Ministry of the Environment
Pfizer Global Research and Development
PPG Industries
PPG Industries
Proctor & Gamble

PSA Inc.
PSA Inc.
Quinn Emanuel Urquhart & Sullivan, LLP
Sapphire Group
Shell Inc.
Silicones Environmental Health and Safety Council
Society for Risk Analysis
Society of Toxicology
State of Maine
State of New Mexico
State of Oregon
State of Texas
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Styrene Information and Research Center
Sudbury Integrated Nickel Operations, a Glencore compa
Summit Toxicology
ToxServices
ToxStrategies
ToxStrategies
ToxStrategies
U.S. Air Force
U.S. Air Force
U.S. Army
U.S. Army Corps of Engineers
U.S. Borax
U.S. Consumer Product Safety Commission
U.S. Consumer Product Safety Commission
U.S. Consumer Product Safety Commission
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U.S. Consumer Product Safety Commission
U.S. Environmental Protection Agency
U.S. Environmental Protection Agency
U.S. Food and Drug Administraton
U.S. National Institute of Occupational Safety and Health
U.S. National Institute of Occupational Safety and Health
U.S. National Institute of Occupational Safety and Health

U.S. National Library of Medicine
U.S. National Library of Medicine
Underwriters Lab- Environment
Vanadium Producers & Reclaimers Association
Versar
Versar
Versar
Vinyl acetate council
Waste Management
Water Environment Research Foundation

Project Description

Proposal to review acrylonitrile IRIS external draft and prepare public comments for submittal. Evaluating whether EI
TERA organized an independent expert panel to review a draft work plan for a Creel/Angler Survey at a contaminate
Review EPA design for environment text on flame retardants.
This project is an enhancement of the ARA Dose Response Framework that was produced in the Beyond Science &
For Beyond Science & Decisions, continuation of case study 17. Low dose linear extrapolation in log-probit space.
Develop a kids risk webpage, in part.
Build on previous work to develop RfD, including critical evaluation of issues, identification of POD, and uncertainty fa
TERA will review DINP toxicity data and provide expert opinion on relevance of chronic cancer animal bioassays resu
Conduct mode of action assessment for liver tumors in mice exposed to diethanolamine.
Assessment Science and Policy's (ARASP) Weight of Evidence Workshop.
Reviewed studies to determine critical effect(s); prepared manuscript; submitted, prepared, and presented 2 SOT pos
Analyze the current display of the uncertainty and variability in the IRIS summaries. TERA will investigate approache
Co-writing a paper on Bayesian approach to developing RfDs
ITER (International Toxicity Estimates for Risk) Peer Review Program for TCDD.
Presentation of recent ecological TBBPA data at SETAC in 2014.
Provide assistance in developing and presenting a continuing education course at AIHce to support OELs by using th
Gift letter funding the mutagenic mode of action adverse outcome case study.
Conduct BMD analysis of key studies and review data for other studies worthy of modeling for perfluorohexanoic acic
Revise rat PBPK model of propyl series compounds, prepare report and poster, present poster at SOT 2011.
Develop proposal for conducting safety assessment case studies for selected cleaning product ingredients.
Organize workshop on scientific issues regarding asthma and cleaning products.
Prepare a manuscript for submission to a peer-reviewed journal that describes the results of developing a framework
The proposed work includes (1) further developing the draft framework, (2) expanding the case study for the applicati
Developing risk values (permissible daily exposures; PDEs) to calculate toxicology-based limits for drug substances a
Organize and conduct subject matter expert workshop on term and definitions of toxic syndromes for NLM CHEMM p
Develop content for additional chemicals in CHEMM.
Brief assessment of the validity of conclusions some commenters have attributed to the Cantor et al. (2010) paper.
ORNL Health Advisory Guidance. Respond to EPA comments on revisions to draft guidelines for authors of EPA Offi
Scoping assessment of vinyl acetate PBPK models for possible use in US EPA IRIS asssessment.
Scoping assessment of PBPK models for possible use in US EPA IRIS assessment of acetaldehyde.
Develop brodifacoum model based on warfarin model; develop bromadiolone model if feasible.
PBPK modeling support for US EPA IRIS assesesment of PCBs.
"Quick Response Statistical Report" EPA Contract No. EP-C-09-006. QA of Hissink et al. 2007 PBPK model for 1,2
Contaminated site necessitates review and possible court testimony on the plaintiffs' side regarding comparison of le
Attend the BSOT annual meeting and make a presentation.
Review the CalEPA Env Health Screening Tool and provide comments at a "meeting of academics" as well as writter
Provide a peer review on evaluation of the weight of evidence for endocrine disruption potential based on all 11 EDS
Investigate mode of action for ethylene oxide-induced lung tumors in male mice. Project through NCTR CRADA.
Draft ecological manuscripts for TBBPA.
An emergency response course for the EHS team, and perhaps individuals from other companies.
Preparation of a Test Plan document, with robust summaries, for chemicals as identified by the sponsor for submissi
2-day Emergency Medical Response training course offered to Chevron.
Evaluate the health risks associated with outdoor wood fired boilers.
Develop a kids risk webpage, in part.
Develop a benchmark dose (BMD) for 5-HMF.
Provide senior-level peer review and comment on several individual susbtance report developed by CTC.
One day meeting in West Virginia to review available tox data and scientific support for the WV screening level. TER
Develop a manuscript based on the previously developed issue paper with a critical analysis of current acute inhalati
Prepare and assist in preparation of manuscripts from the nuclear receptor workshop.

Chair session on soil exposure at the July 2011 Tox Forum meeting.
BMD course (related to Boot Camp) and DR 1 and 2.
Review and revise industrial hygiene guides and occupational exposure limits (OELS).
Application of uncertainty factor for the development of the IHG. Submission of literature search results and IHG docu
Identify, gather, review and assemble available data on chemicals as defined in the ELSIE document Safety Databas
Review EPA's text entitled: Application of Quantitative Data to Develop Data-Derived Extrapolation Factors for Inters
Case study review for Workshop 9: Adverse outcome pathway (AOP) for arsenic carcinogenesis - 1/2 day - and non
Development of OEL documents for pharmaceutical compounds.
Develop course training package, descriptions and outlines of all courses and review EnRisks portions. Being submi
Determine cancer slope factors for DINP using California proposition 65 logic and EPA (2005) guidelines.
Alaska DEC has tasked TERA with conducting an independent, expert peer review of the available reference doses f
BMD modeling support for aminoethylethanolamine, evaluate relevance of endpoints and endpoints to combine for m
Critical review of available information on decalin (decahydronaphthalene) to confirm if histopathological changes obs
Assist in developing risk assessment procedures.
Met with sponsor to discuss options for IRIS reinvention.
Development of a periodic newsletter.
ITERate (International Toxicity Estimates for Risk) Peer Review Program: Manganese oxide.
Comment on and contribute to manuscript on issues and assumptions behind arguments made to invoke linear low-d
Provide comments on EPA IRIS assessment for TCE to EPA's Scientific Advisory Board.
Procure and translate Japanese studies on 1,4-dioxane; develop analysis and publish a manuscript.
Route-to-route extrapolation of NOAELs and LOAELs from existing and new studies conducted by the oral route to in
Letter review of phthlataes.
Peer review of risk assessment documents on PFOS and PFOA with emphasis on dose response.
Letter peer consultation on flame retardant dechlorane plus.
Review a 4-5 page special issue paper on boron dealing with PBPK, BE and uncertainty.
Letter Consultation on 3 flame retardants.
Assessment AEEA and Ethyl.
CoCAM 5. Three assessment peer reviews.
Review of petroleum substances.
TERA organized and conducted an independent peer consultation of the draft screening assessment of substituted d
Review documents provided by HC: draft Screening Assessment reports and outlines and templates for documenting
Coordinate and manage an independent peer consultation of the draft screening level health assessment for methyle
Develop a guidance document for using biomonitoring studies to estimate exposures for conducting human health ris
Position paper and internal Health Canada peer consultations on risk assessment for short-term exposures to chemic
Custom 3-day Boot Camp course.
Peer review of Batch 12 substances N,N-diphenyl -guanidine; carbon black; cristobalite; quartz; alkyl derivs pyridine.
Letter peer consultation on flame retardants tricresyl phosphate (TCP).
Letter peer consultation on 2 flame retardants, bis(2-ethylhexyl) tetrabromophthalate(TBPH)/2-Ethylhexyl-2,3,4,5-tetra
TERA will select a minimum of 5 Canadian Public Health Summaries, based on recommendations from Health Cana
TERA organized and conducted a letter peer consultation on two draft guidance documents: cumulative risk for phtha
Assessment of Non-Cancer Effects due to Short-Term Exposure and Short-Duration Toxicity Reference Values (TRV
Update and complete the human health screening risk assessment report for acetone. This will include data gatherin
(1) prepare "toolbox" of risk assessment methods; (2) framework and discussion of issues related to risk assessment
Organize and conduct independent scientific peer consultation on two draft Health Canada screening assessment re
Organize and conduct an independent scientific peer consultation on the draft Health Canada screening
Coordinate and manage an independent external scientific and technical peer review of the Canadian Coarse Particu
Review of screening assessment for triclosan.
Review exposure scenarios for azo dyes.
Conduct peer consultation of the revised hydrogen sulfide assessment document. TERA did initial review in fall 201
Peer consultation of the revised State of the Science report on 1,1-biphenyl.
Organize and conduct letter peer consultations on petroleum stream products.

Letter peer consultation on 4 azobenzidine assessments.
Organize and conduct independent scientific opinion on the Health Canada documents on acrylonitrile. The objective
Organize and conduct letter reviews on Petroleum Stream Products.
Organize and conduct a second letter peer consultation on petroleum stream products.
Organize and conduct independent scientific peer consultation on the Health Canada screening assessments
Organize and conduct independent scientific peer consultation on the Health Canada screening assessments: (79-
TERA will review rat-human dosimetric models and evaluate for diesel exhaust exposure (Part 1) and determine a hu
Participate in 2-day workshop on current state-of-knowledge in the health risk assessment approaches for drinking w
Quantitative Uncertainty and Variability Analysis of Perfluorinated Chemicals (PFCs) Clusters- Perfluorooctane Sulfo
The goal of this project is to finalize the content for about 50 potential mass casualty chemicals and about 23
Case study review for Workshop 9 – flame retardant framework - for addressing risk and screening alternatives from
Dose-response evaluation of relationship between Trans-fat intake and LDL-cholesterol. Phase I - scoping: Deliver a
Review of NZ risk methods document.
Carry out a review of the Hobsonville Health Risk Assessment undertaken by Golders Ltd as commissioned by the H
Written peer review for health assessment titled Health risk assessment of diluted Kiwicare No Borer, ESR client
Task 1: Technical Information Resources: TERA would provide ESR with a list of contacts and reference
Technical review and detailed comments relating to the review of the report entitled "A Screening Level Risk Assessr
Technical review and detailed comments relating to the review of the report entitled "A Screening Level Risk Assessr
Provide two presentations (40-60 mins) on "Principles for the risk assessment of mixtures" and "Cancer and non-can
For Health Canada, TERA organized and managed an expert scientific letter review of a Health Effects Indicator (HE
For Health Canada, Development of assessment materials to be used for evaluating Biologist (BI-02, 03, 04) and Ch
For Health Canada, development of a proposed approach for identifying polymers that pose known or potential high l
Review and comment on new CatReg software interface.
Providing services for Dept. of Energy (DOE), Office of River Protection (ORP). Tank Vapor Management Expert Par
Prepare comments on the trichloroethylene IRIS document on issues related to cancer WOE finding and sensitivity a
Develop and deliver an OEL presentation.
Provide support for development of dose-response analyses for tumorigenic effects observed in mice administered c
Conduct a letter peer review of a methanol cancer bioassay published as Soffritti et al. (2002).
Rview of information regarding acrylamide in coffee.
TERA hosted and organized a workshop on the Endocrine Disruptor Screening Program Tier 1 experience. The mult
Workshop III of Beyond Science and Decisions- to continue the discussion toward a unified approach to dose respon
Prepare response to proposed HPV program test rule.
Develop white paper on aggregate and cummulative risk for OPPT.
Provide review of document regarding recommended cleanup of broken mercury thermometers.
Develop publication based on the screening level health assessment on exposure to mercury from broken compact fl
Review and comment on draft manuscript on reference value for nickel in ambient air: deriving human equivalent co
Conduct a meta-analysis and meta-regression of respiratory cancer risk following exposure to nickel compounds. Th
Monitor progress of research related to evaluation of nickel MOA; provide advice to NiPERA on the research project(
Review and rate proposals related to nickel MOA; monitor progress of funded work; provide advice to NiPERA on the
Facilitate the development of a WEEL.
(1) Evaluate of toxicity of emerging contaminants to provide Sponsor with a scientific review of chemical risk assessn
Run CatReg model for one set of data with chronic progressive nephropathy (CPN) as the endpoint.
Add new data to ITER from NSF International.
Evaulate the MOA and safety studies on DMAA; contribute to the writing of a paper on DMAA, along with NSF.
Review of polymer toxicity information.
Present lecture on environmental risk assessment at Ohio State University.
Review Ontario MOE approaches to setting air standards. Conduct research into how other jurisdictions address sim
Provide support for development of dose-response analyses for tumorigenic effects observed in male rats administer
Changed dioxane publication to open access.
Conduct Japanese study translation and anaylsis in part.
Determination of whether the current TTC limits are protective for developmental/reproductive toxicity endpoints.

Manage registration and workshops for 2011 TRAC conference.
Provide assistance with online and onsite registration, catering details and workshop management and deployment fo
Review information on petroleum coke and related materials to assist in understanding possible toxicity to defined ex
Respond to reviewer comments, edit acrylamide manuscript, review proofs.
Communicate toxicology related to siting a plant in Pittsburgh.
Gather and consolidate SEHSC data in order to develop a summary of all relevant data on D4 and D5 into WEEL do
Compile information on local contacts at universities for student award for DRSG. Student/intern work paid by grant f
Host SOT 2013 Global Senior Scholar Exchange program. The program aims to increase the global impact of toxicol
Examine whether current pesticide residues have the potential to affect the lobster industry in Maine directly or via
administration of the RCRA Permit for the Waste Isolation Pilot Plant (WIPP) site in New Mexico.
Review of in vitro study conducted by private party to determine likely bioavailability of ingested arsenic in mine tailing
Organize and hold a workshop on technical and scientific issues related to ozone NAAQS.
Organize and conduct scientific peer review of chemicle-specific development support documents which outline the h
Add new data from TCEQ to ITER in the ITER column.
Enter Hexavalent Chromium toxicity factors from the chromium development support document on the ITER databas
Organize an external technical letter review of the TCEQ draft Development Support Document (DSD) for carbon dis
Enter Nickel Toxicity Factors from Nickel Development Support Document on the ITER Database.
Conduct a letter peer review of TCEQ's revised ESL (effects screening level) guidelines, including identifying potentia
Letter peer review with follow up teleconference of section 4.2 Carcinogenic Potential of the development support do
Letter peer review of section 4.3 Carcinogenic Potential od the DSD for isoprene.
Review CalEPA chloropicrin cancer risk assessment.
Review draft MSDS forms provided by SRC for format and content. Editing of forms as needed for ANSI format com
Technical support for public workshop on mouse lung tumor mode of action issues (for ethyl benzene, styrene and
Review and comment on Quebec 24-hour nickel standard.
Work with Sean Hays of Summit Toxicology to add biomonitoring equivalents data to National Library of Medicine ITE
Conduct literature search, retrieve papers, and write toxicokinetics chapters for the following chemicals: acetochlor, a
Organize and conduct a letter peer review of a rat 90-day study, conducted as part of a series of studies designed to
Organize and conduct a letter peer review of a mouse genomics study, conducted as part of a series of studies desig
ITERate review of chromium VI.
Conduct focused science reviews of up to 6 chemical risk assessments that assess regulatory interpretation of the sc
Conduct a 4-day boot camp course on-site at WPAFB.
Form an expert panel and conduct a technical review of two occupational exposure levels (OELs) and the methods
2a. Prepare slides in support of Task 1 (problem formulation) -- draft and final -- including soliciting AFCEC input
Develop manuscript on the previous work we did in developing an independent OEL for borates.
Develop and deliver a course on mixtures risk assessment issues.
Review and compile data relating to human exposure to selected flame retardants.
Cconduct literature searches regarding the concentrations of specified elements (antimony, arsenic, barium, cadmiur
Conduct research regarding the production and use of specified phthalates. Results of the TERA research will be use
Conduct research regarding the production and use of specified plastics with regards to the possibility if containing ar
Review epidemiology and toxicology literature on common molds.
Review literature and prepare hazard characterization (tk and toxicity sections) and exposure text on TCEP. Identifie
Conduct a broad, high-level , letter peer review of the CPSC Chronic Hazard Advisory Panel (CHAP) report on Phtha
Organize exposure data on flame retardants into database for use in exposure assessment.
Conduct research regarding the production of engineered wood products and research on the possibility and concent
Conduct a letter peer review of a CPSC draft report on Nanomaterial Toxicity and specifically assessing nanosilver, r
Review Technical Qualifications Document provided by NHEERL. Review evaluation criteria and guidance. Particip
TRAC Conference - TERA to manage social, registration, oversee catering at hotel and other items as requested.
Organize and conduct a 3 day boot camp course.
Create and publish TRAC2016 website, work with TRAC committee and provide onsite support to 2016 TRAC confer
Create and publish TRAC2014 website, work with TRAC committee and provide onsite support to 2014 TRAC confer
Give presentation to NIOSH staff on the use of basic research in developing risk assessments for occupational settin

Peer consultation workshop for NLM CHEMM to agree on terminology and definitions.
Continued lease, maintenance and update of ITER database for use on TOXNET.
QA of ingredient reviews and guide to preparing a toxicological assessment.
Evaluation of K-Ras and cII mutations in the lungs of Big Blue mice exposed to vanadium pentoxide. The results will
Review of Consumer Products Safety Commission on metal levels in toys.
IRIS external peer review of hexachloroethane.
Review CPSC assessment on cadmium in children's metal jewelry.
Phase I in potential evaluation of vinyl acetate MOA. Conduct validation, cytotoxicity and mutagenicity studies in gpt
Support the development of a collaborative effort on 1,4-dioxane risk assessment.
Identify and assemble data on health and ecological endpoints to support an EPA risk assessment model for chemic

Project Type
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Government
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Government

Government
Government
Non-Profit
Private Sector
Government
Government
Government
Collaboration
Collaboration
Non-Profit

To: Palich, Christian[palich.christian@epa.gov]
Cc: Beck, Nancy[Beck.Nancy@epa.gov]; Baptist, Erik[baptist.erik@epa.gov]; Lyons, Troy[lyons.troy@epa.gov]; Fugh, Justina[Fugh.Justina@epa.gov]
From: Dourson, Michael (doursoml)
Sent: Tue 9/5/2017 12:45:03 AM
Subject: Re: Response to Senator Carper
image001.jpg
Question 1-2014 Annual Report.pdf
Question 1-2015 Annual Report.pdf

Christian

Here are the attachments for question 1.

Cheers!

Michael

— Risk Science Center (formerly TERA Center) sponsors the International Toxicity Estimates for Risk (ITER) database of risk assessment values on Toxnet: http://toxnet.nlm.nih.gov/

Risk Science Center
Department of Environmental Health

From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Monday, September 4, 2017 at 8:42 PM
To: "Palich, Christian" <palich.christian@epa.gov>
Cc: "Beck, Nancy" <Beck.Nancy@epa.gov>, "Baptist, Erik" <baptist.erik@epa.gov>, "Lyons, Troy" <lyons.troy@epa.gov>, "fugh.justina@epa.gov" <fugh.justina@epa.gov>
Subject: Response to Senator Carper

Christian

Please find attached my response to Senator Carper. This set includes a slightly revised letter and responses to individual questions. Attachments for questions 1, 2, 6, and 9 will come in separate emails. The attachment for question 3 is still under development.

Of course, all of this is draft and comments are welcome.

Cheers!

Michael

-- If you can't explain it simply, you don't understand it well enough. Albert Einstein

From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Sunday, September 3, 2017 at 4:22 PM
To: "Palich, Christian" <palich.christian@epa.gov>
Subject: Re: Opening Statement of Michael Dourson

Christian

Please find attached my letter to Senator Carper to be sent with my responses to his questions. I would be happy to take comments on it.

Cheers!

Michael

—The right to search for the truth implies also a duty; one must not conceal any part of what one has recognized to be true. Albert Einstein.

From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Friday, September 1, 2017 at 3:19 PM
To: "Palich, Christian" <palich.christian@epa.gov>
Subject: Re: Opening Statement of Michael Dourson

Christian

This will not be a problem. Have a nice weekend.

Michael

-- *Risk Science Center (formerly TERA Center)*
Integrating assessments for both human and environmental health. See
http://www.tera.org/EcoTERA/index.html

From: "Palich, Christian" <palich.christian@epa.gov>

Date: Friday, September 1, 2017 at 12:57 PM
To: Michael Dourson <doursoml@ucmail.uc.edu>
Cc: "Fugh, Justina" <Fugh.Justina@epa.gov>, "Lyons, Troy" <lyons.troy@epa.gov>, "Shimmin, Kaitlyn" <shimmin.kaitlyn@epa.gov>
Subject: RE: Opening Statement of Michael Dourson

Thanks Dr. Dourson,

If you could please provide the supporting documents for these questions by Tuesday September 5th that would be great so we can quickly turn this around to Ranking Member Carper by the 6th.

Have a great weekend,

Christian R. Palich

Deputy Associate Administrator

Office of Congressional & Intergovernmental Affairs

U.S Environmental Protection Agency

O: 202.564.4944

C: Ex. 6 - Personal Privacy

E: Palich.Christian@epa.gov

From: Dourson, Michael (doursoml) [mailto:doursoml@ucmail.uc.edu]
Sent: Friday, September 1, 2017 10:35 AM
To: Palich, Christian <palich.christian@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>
Subject: Opening Statement of Michael Dourson

Christian

Here is a revised opening statement, and also a draft of my response to Senator Carper. I am still working on the attachments to this draft response and will send you a more complete draft response next week with attachments. This attachment is just to give you a sense of where I am heading. Also, Justina Fugh will be drafting what are likely much more appropriate answers for questions 10, 11 and 12.

Comments welcome.

Cheers!

Michael

-- If you can't explain it simply, you don't understand it well enough. Albert Einstein

Toxicology Excellence For Risk Assessment (TERA)

contents

Mission/Vision/Core Values

Toxicology Excellence for Risk Assessment (TERA) is a non-profit and tax-exempt organization designed for scientific and educational purposes.

Mission

To support the protection of public health by developing, reviewing and communicating risk assessment values and analyses; improving risk methods through research; and, educating risk assessors, managers, and the public on risk assessment issues.

Vision

TERA was founded on the belief that an independent non-profit organization can provide a unique function to protect human health by conducting scientific research and development on risk issues in a transparent and collaborative fashion, and communicating these results widely.

Core Values

TERA is an independent non-profit and as such we embrace our core principles and values in all our activities. These core principles guide day-to-day TERA operations - from our consideration of new projects and sponsors, to our scientific evaluations and communication of results.

- Honesty and integrity
- Independence
- Transparency
- Collaboration

Board of Directors

DATE INDICATES YEAR OF CURRENT ENDING TERM

Michael Dourson, PhD
President Toxicology Excellence for Risk Assessment
(1/1/2015 – 8/1/2015)

Patricia McGinnis, PhD (2017)
Interim President Toxicology Excellence for Risk Assessment

Gail Charnley Elliott, PhD (2015)
HealthRisk Strategies

Mike Fremont, PhD (2014)
Rivers Unlimited

Jennifer L.S. Knaack, PhD (2015)
Department of Pharmaceutical Sciences College of Pharmacy & Health Sciences Mercer University

Laurie Kraus, PhD (2016)

James Rock, PhD (2016)

Gregery S. Romshe, CMA (2015)
VICE CHAIR and FINANCE COMMITTEE CHAIR
The Procter & Gamble Company

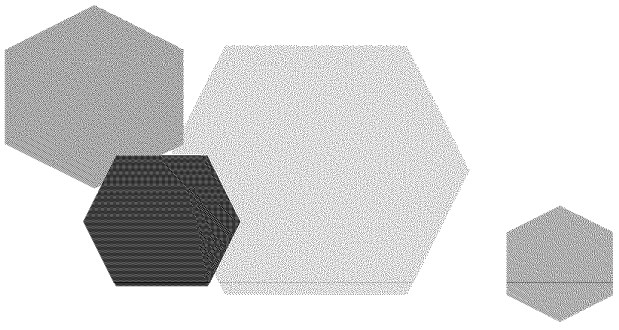
Jon L. Seymour, PhD (2014)
AUDIT COMMITTEE MEMBER

Martin L. Stephens, PhD (2016)
Johns Hopkins Center for Alternatives to Animal Testing

Philip E. Tobin, PA-C, MPAS (2016)
NOMINATING COMMITTEE MEMBER
Department of Physician Assistant Studies

James D. Wilson, PhD (2016)
CHAIR

Chase D. Wright, CPA (2016)
AUDIT COMMITTEE CHAIR



News from TERA's President and Board of Directors

TERA Joins the University of Cincinnati

Toxicology Excellence for Risk Assessment joined the Department of Environmental Health, at the University of Cincinnati's (UC), College of Medicine on July 6, 2015. TERA will be known as the Toxicology Excellence for Risk Assessment Center (or TERA Center).

TERA was organized in 1995 as a nonprofit with a mission to support the protection of public health through the best use of toxicity data. Now as a Center with the Department of Environmental Health at the University of Cincinnati's College of Medicine, we continue to accomplish this mission through independent evaluation of toxicity data and by interpreting and communicating risk assessment information through assessments and websites, organizing peer reviews and consultations, improving risk methods through research, and educating risk managers, assessors, and the public on risk assessment issues. TERA has a strong history of enhancing the use of chemical-specific data to increase the rigor and transparency of evaluations aimed at the prevention of potential human health risks.

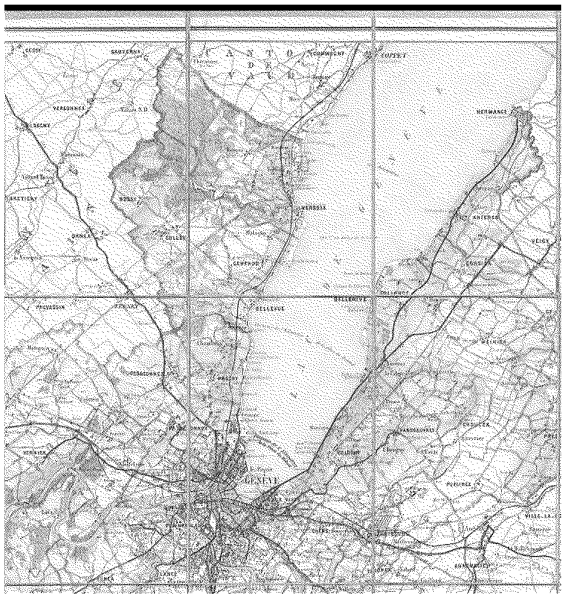
The TERA Center will maintain this rigor and transparency, but will also mesh its work with the research findings of UC investigators in order to develop the next generation of risk assessment methods based on Toxicology 21 principles.

SUPPORTING MISSIONS

TERA Center: To support the protection of public health by developing, reviewing and communicating risk assessment values and analyses; improving risk methods through research; and educating risk assessors, managers, and the public on risk assessment issues.

UC-DEH: To improve the quality of life by identifying the mechanisms of disease and injury due to environmental exposures and genetic factors, and by developing effective methods of preventions and interventions.

Global impact



Geneva

9/14/2015 – 9/25/2015

Dr. Michael Dourson served on the 2015 Joint Meeting of the Pesticide Review panel to determine the appropriate acceptable daily intakes and exposures for up to 20 pesticides.

The meeting was highly interactive and impactful.

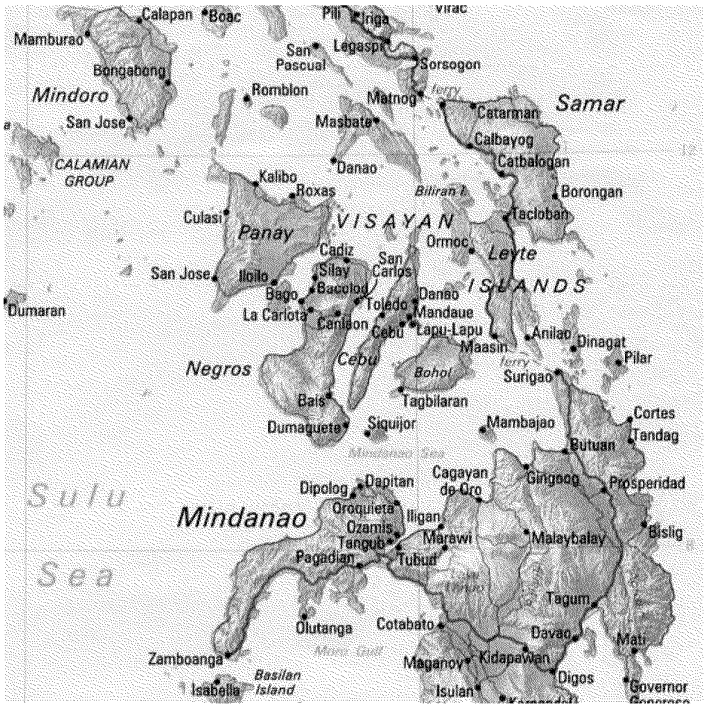
A report is available at the World Health Organization website.

Philippines

8/25/2015-8/31/2015

Dr. Michael Dourson served as a US delegate to the Asian Pacific Economic Conference held in Cebu, Philippines, where he gave several lectures on metal toxicity, and led a small study group on methyl mercury contamination of fish.

This organization meets periodically to share technology among member states.



A busy year...

TERA brings RISK ASSESSMENT PERSPECTIVE to Nutrition Science

In a novel approach

to addressing the effect of consumption of a macronutrient, TERA has conducted an evaluation of the relationship between the intake of trans fatty acids (TFAs), particularly industrially-produced TFAs (iTFAs), and changes in plasma low density lipoprotein cholesterol (LDL-C), particularly in the low intake region.

A key issue was evaluating the shape of the dose-response curve in the low-dose region. TERA took a two-pronged approach to address the issue. First, the mode of action (MOA) for the impact of TFA on plasma LDL-C was evaluated. Second, TERA conducted a meta-regression of the controlled clinical trial data on iTFAs, using (MCMC) modeling, in collaboration with Bruce Allen for the modeling, and DeAnn Liska of Biofortis for the nutritional perspective.

This approach was unique in nutritional literature, in rigorously considering a variety of flexible curves, including both linear and nonlinear models. The MOA analysis concluded that, although there are several data gaps precluding a rigorous application of the evolved Hill Criteria for evaluation of MOA, the feedback loops and homeostatic controls responsible for maintaining homeostasis of cholesterol and triglyceride levels result in a less than linear relationship between TFA and LDL-C. Consistent with the MOA evaluation, the meta-regression found that an S-shaped curve fit by the Hill model is clearly better than linear model, and linear model is not acceptable.

This novel analysis has generated much interest in the nutrition and risk assessment communities. It has been presented at several venues, including the ToxForum, and SOT-FDA Joint Colloquium; publications are in preparation.

This work was sponsored by the ILSI North America PHO Task Force.

Ozone NAAQS Science and Policy Workshop Report Now Available

Working with the Texas Commission on Environmental Quality (TCEQ) and others, TERA organized a public workshop in April 2015 to provide an independent evaluation and synthesis of key considerations for EPA's November 2014 proposal to lower the primary National Ambient Air Quality Standard (NAAQS) for ozone. A diverse group of well-known and respected science and policy experts engaged in robust discussions on key issues, so that TCEQ and other attendees could gain a better understanding of the issues and implications. This multi-disciplinary group of science and policy experts deliberated on the nexus between scientific findings and implications for public health. The focus was on science related to the level (concentration) of the primary NAAQS and an independent evaluation and synthesis of key policy and other considerations for approaching the difficult and important ozone NAAQS decision.

Presentations, background materials and a summary report are available at http://www.tera.org/Peer/ozone/index.html.

Framework for Addressing Less-than-Chronic and Intermittent Exposures

How does one identify an exposure limit (toxicity reference value, or TRV) for an intermittent exposure (e.g., one day/month for 40 years)? Should one use an acute or a chronic limit for this sort of scenario? How does one decide?

Intermittent exposures such as these are common in many sectors, including manufacturing, waste site cleanup, food safety, and consumer product exposures. Led by Lynne Haber and in collaboration with Bette Meek and Health Canada scientists, the TERA team developed a framework for addressing such scenarios. The framework presents an integrated, tiered approach that assists the user in identifying when existing TRVs can be applied directly, and the adaptations needed to assess the acceptability of short-duration or intermittent exposure scenarios. A manuscript based on the framework is nearing publication, and Dr. Haber shared the framework in a Risk Assessment Specialty Section webinar.

See http://www.toxicology.org/groups/ss/RASS/downloads.asp.

TERA Scientists Assist With Harmonization Effort in Pharmaceutical Industry

Like other industries, the pharmaceutical industry has to manage chemical safety issues—both for workers and consumers. The TERA Center has been working with toxicologists and risk assessment scientists from pharmaceutical industries, consulting groups and academia to discuss current practices for exposure limits, evaluate inconsistencies across guidance documents, identify key areas for harmonization, and document best practices for risk assessment of pharmaceuticals.

"Harmonization doesn't necessarily mean standardization," says Andrew Maier, PhD, an associate professor in the Department of Environmental Health and TERA Center co-director. "It's more a matter of understanding the basis for safety so that we enable savvy users of the risk assessment materials.

Maier and Alison Pecquet were key organizers and facilitators for an October 2014 workshop that was convened in New Brunswick, New Jersey, to identify and address further opportunities for advancing harmonization and best practices in deriving and applying acceptable daily exposures (ADE) in pharmaceutical manufacturing operations. The workshop effort was spurred from a benchmarking assessment to compare current methods in risk assessment for pharmaceuticals.

> "During our benchmarking work, we found that the international guidance documents and methods being used were clearly not harmonized in a number of areas," Pecquet says. "The workshop, which involved most of the top global pharmaceutical companies, was an effort to discuss some of the ways that we could harmonize efforts across agencies so that all of these health-based limits for pharmaceuticals are based on consistent methodologies."

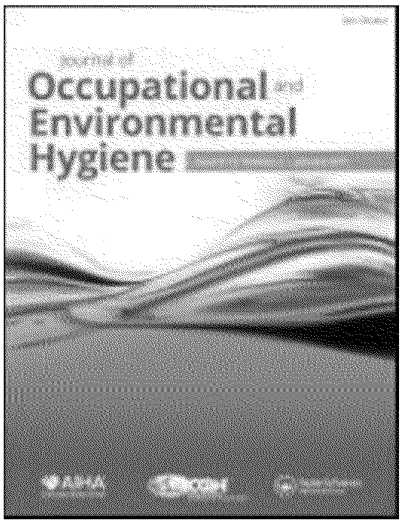
Following the workshop, an article summarizing key workshop findings was published in the September 2015 issue of Contract Pharma, a trade magazine.

The article concluded that a "harmonized set of recognized scientific principles is needed to inform individual efforts in calculating, interpreting, and implementing pharmaceutical risk assessments."

"We are currently working on a series of 10 articles associated with each workshop topic that will appear in a Special Issue of Regulatory Toxicology and Pharmacology in early 2016," Pecquet says. "Our goal is for these reports to shed light on inconsistencies and data needs, lead to further research of the knowledge gaps and contribute to informing decision making among risk assessors in the pharmaceutical industry by providing a 'guide to best practices.'"

"Ultimately, we aim to have one publication that summarizes key issues in this area to help users harmonize and use best practices, all in one place."

SPECIAL ISSUE: State of the Science of Occupational Exposure Limit (OEL) Methods and Guidance



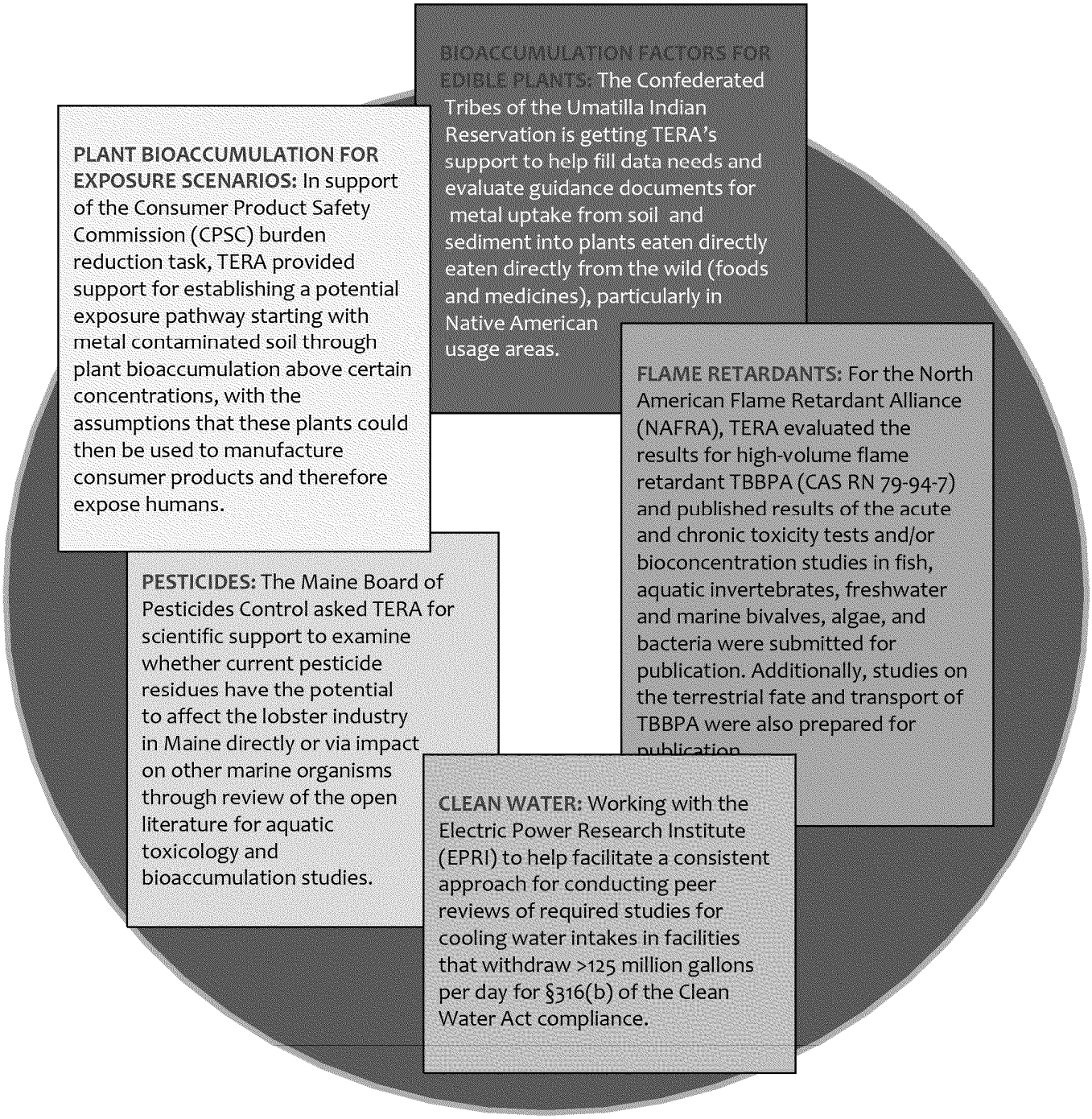
The National Institute for Occupational Safety and Health (NIOSH) conducted an effort to identify and characterize leading issues pertaining to OELs and their development through research, which culminated in a collection of articles focused on each key issue. Those articles and the key issues they explore comprise a Special Issue of the *Journal of Occupational and Environmental Hygiene*. The goal of this effort is to describe the issues related to education and communication of science principles and to understand how they can be incorporated into (and thereby impact) the practices of OEL development and interpretation. Focusing specifically on the state-of-the-science in the fields of exposure science, occupational hygiene, risk assessment, and toxicology this effort sought to provide a clear description of how advances in these research areas can contribute to the practice of OEL setting—by reviewing the methods used for most OELs that are currently available as well as new methods that are actively being incorporated in the OEL process. An essential topic included within the set of complementary and interrelated articles dedicated to this pursuit is the consideration and interpretation of OELs in the context of evolving risk management practices. The articles are intended to serve as a current critical review of occupational risk assessment methods that will enable occupational hygiene professionals to have a clear understanding of the science methods incorporated in the OELs they develop or use.

The ten articles in the supplement resulted from collaborations among scientists at NIOSH, Toxicology Excellence for Risk Assessment (TERA) Center (Dr. Andrew Maier, Dr. Lynne Haber, Dr. Michael Dourson, Dr. Bernard Gadagbui), and other organizations.

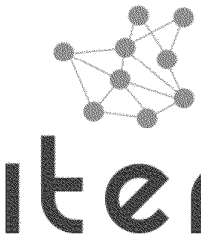
While the list of topics for OELs covered in this supplement is in no way exhaustive, it does represent some of the most relevant, promising, and readily applicable scientific advances that can be integrated into risk assessment and management of occupational hazards. The purpose of this collection of article is to inform the practitioner, stimulate the researcher, and provide a basis for more protective and scientifically sound guidance and policy.

TERA's Eco Risk Assessment portfolio is growing!

Ms. Alison Pecquet, M.Sc. and Dr. Charles Pittinger, TERA Fellow, along with additional TERA staff and external collaborators are working to provide support for environmental risk-related services.



Partnerships



A collaborative effort to organize the world's risk data

Through the Alliance for Risk Assessment, a group of organizations have come together to build the world's premiere database of human health risk values. Building from TERA's *International Toxicity Estimates for Risk (ITER)*, this effort has been dubbed *ITER+* and seeks to first expand the database offerings to include the European Union's Derived No Effect Levels (DNELS), and then additional values to be determined. *ITER* is currently available via the National Library of Medicine, and includes risk values from EPA, ATSDR, IARC, IPCS, and more. The *ITER+* Advisory Committee is responsible for prioritizing the addition of risk values from new sources.

Situation: Exposure analysis requires the use of reference values to qualitatively understand exposure data. Currently, these values are developed by a number of researchers and/or authoritative bodies and reside in a variety of locations. Searching for these values can be time-intensive, values identified can be of varying scientific quality, and often additional expertise is needed to conduct a screening level exposure assessment.

Proposal: Build upon the existing data housed within the International Toxicity Estimates for Risk Assessment (*ITER*) database to include additional values needed for exposure and risk assessment. *ITER* includes peer-reviewed human-health risk values and is searchable using the Toxicology Data Network (TOXNET) on the National Library of Medicine's website (**http://toxnet.nlm.nih.gov/newtoxnet/iter.htm**).

The Alliance for Risk Assessment is organizing a collaborative public/private partnership for the systematic addition of credible values to *ITER+*. The new additions will include the health basis of the value and any assessment or uncertainty factors needed for the lack of key data. These additions will be for chemical ingredients that are known to be used or are found in consumer products. As the initial start for a systematically-phased project, REACH data for derived no effect levels (DNEL) for about 600 chemicals will be added, followed by derived minimal effect levels (DMEL), and the values for the 100 most commonly found

chemical ingredients in consumer products. This focus could encourage analysts to use *ITER+* as their initial 'go to library' site prior to undertaking a full literature search.

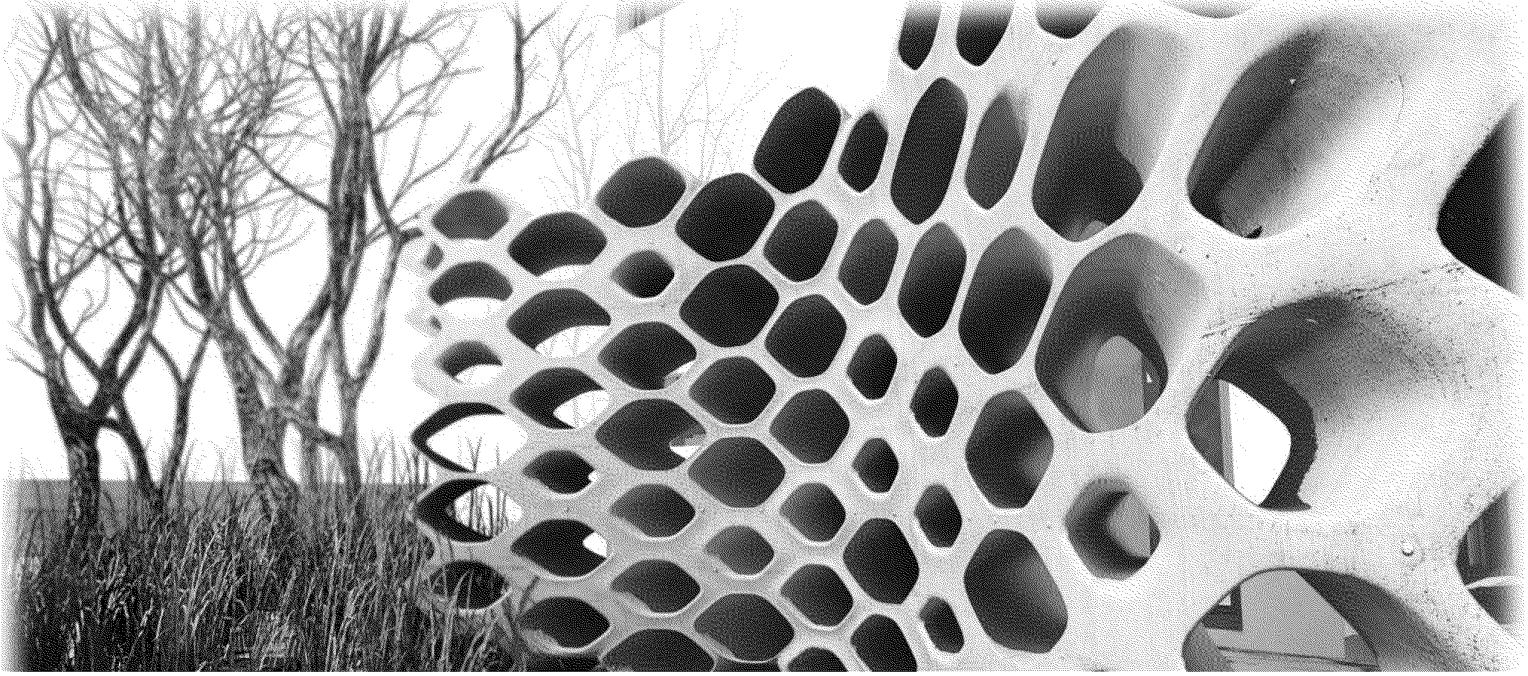
Value: Centralizing authoritative reference values from global organizations in a curated database will streamline the risk assessment process, and foster the consideration of exposure for consumer products by removing one of the current barriers to the use of screening level exposure analysis.

The Alliance welcomes additional partners interested in helping to build ITER+, whether through financial or in-kind support. Additional information can be found at www.allianceforrisk.org.

BIG DATA

Turning Big Data to Knowledge (BD2K): A discussion of the NIH BD2K initiative and how it might advance the practice of Toxicology and Risk Assessment: The fields of toxicology, pharmacology and risk assessment are undergoing a revolution in the use of pathway-based approaches to evaluate the biological effects of chemicals. These fields would benefit from accessible tools that make big data convenient and intuitive to integrate, analyze, query and visualize. The aim of this ancillary meeting is to reach out to toxicological scientists and introduce them to the NIH big data programs. A panel of researchers provided short overviews of the BD2K and LINCS initiative and thoughts on how big data can be leveraged for protection of people and the environment.

This discussion was held March 23, 2015 Society of Toxicology (SOT) Outreach Meeting in San Diego, California.



Beyond Science & Decisions: *From Problem Formation to Dose-Response Assessment*

9

Workshops
the Workshop series has now completed 9 workshops, bringing scientists of various affiliations and expertise together.

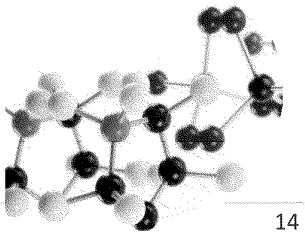
60+

Over 60 organizations
government, industry scientific societies and nonprofits— have contributed to the Workshop's mission to advance the science of risk assessment.

40+

Case Studies
the Workshop series has now reviewed over 40 case studies focusing on a range of risk topics.

Preparation for 2016 Workshop 10 is in underway.



ARA Coalition

1,4-Dioxane Reanalysis of a Regenerative Hyperplasia Mode of Action

EPA's IRIS 2012 external reviewers of the 1,4-dioxane assessment suggested that the histopathology slides from the NCI 1978 dioxane cancer bioassay in mice be reviewed to ascertain whether non cancer pathology was evident. If evident, this finding would support the conclusion that the cancer MOA is regenerative hyperplasia. TERA scientists worked with Dr. Gene McConnell and staff of the NTP to reevaluate these mouse liver slides and found extensive non cancer pathology, thus supporting the regenerative hyperplasia MOA.

This evaluation also suggested the need to re-evaluate the mouse liver slides from a series of Japanese studies on 1,4-dioxane. Five US states and TERA scientists requested the full unpublished reports (including the relevant micrographs) from the study authors. These reports have been reviewed and a draft analysis was prepared.

As described in our draft analysis, the additional information and translations are also supportive of a regenerative hyperplasia MOA but with one exception, specifically, the reported findings from the histopathology and clinical chemistry of the mouse liver in the Japanese studies are contradictory. This may be due in part to the investigators changing the criteria for liver histopathology scoring during the course of reporting their results.

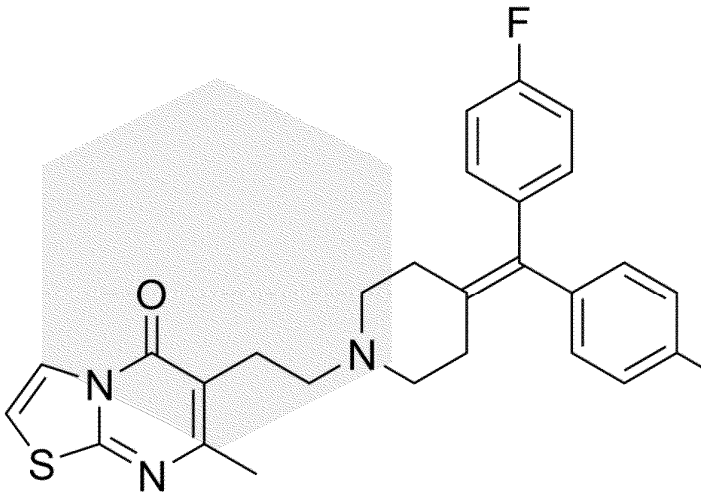
The State of Kentucky petitioned the Alliance for Risk Assessment (*ARA*) Steering Committee to obtain additional histopathology documentation from the Japanese studies to inform 1,4-dioxane's cancer Mode of Action (MOA). The intent of this project is to use this additional information, together with the earlier re-evaluations, in order to reach a conclusion regarding the hypothesized MOA for 1,4-dioxane's liver tumor formation (and potentially other tumors). The coalition includes 5 groups and others are welcomed to participate. An evaluation of the data is being done by 3 pathologists and will be used in the final publication.

More information, including a project timeline, can be found on the project website at http://allianceforrisk.org/14-dioxane-analysis/

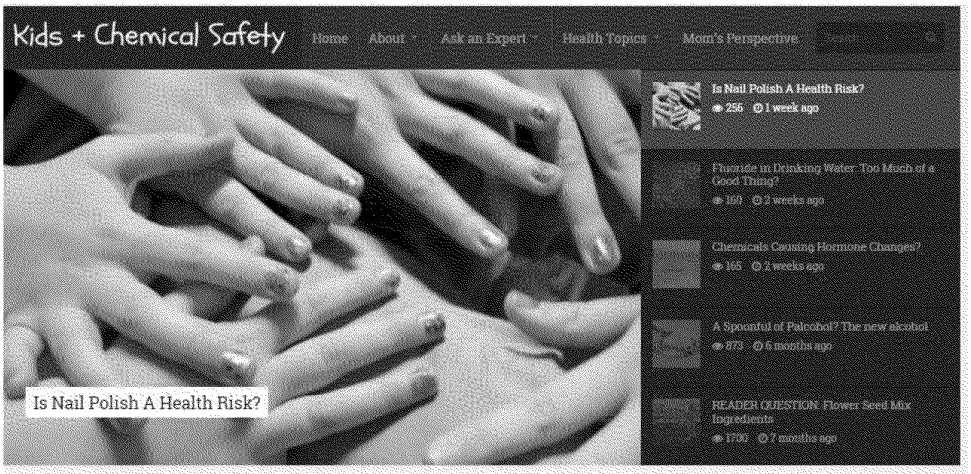
What is *ITER*ate?

*ITER*ate is a new program from TERA to review chemical risk values from published peer-reviewed journals for loading onto the International Toxicity Estimates for Risk (*ITER*) (www.tera.org/iter; http://toxnet.nlm.nih.gov/) Through *ITER*ate, TERA convenes a small group of toxicology and risk assessment experts to evaluate the Enter *ITER*ate. This process will help fill data gaps for missing values or outdated assessments. TCDD example: This controversial chemical has no risk guidance from EPA. The *ITER* database contains data from ATSDR for noncancer endpoints only. The *ITER*ate process was utilized to upload an independently derived cancer value for TCDD. Now, states needing to act to protect human health regarding TCDD have access to this newly derived value.

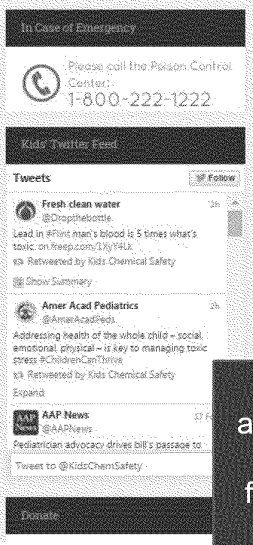
How to Participate Experts in risk assessment are invited to volunteer for review panels. Authors of risk value papers are invited to submit to *ITERate*.



Kids + Chemical Safety



+ Balanced, scientifically accurate chemical health information.



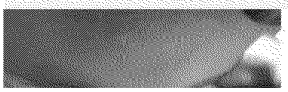
Latest Updates:

Is Nail Polish A Health Risk?

256 1 week ago 0

Moms are not the only ones that think about the health and well-being of their children. Today's "Mom's Perspective" is a "Grandfather's Perspective." My granddaughter, who is with child, dropped by the other day and asked what I was reading? It was an article on nail polish that contained a

Read more



Fluoride in Drinking Water: Too Much of a Good Thing?

160 2 weeks ago 0

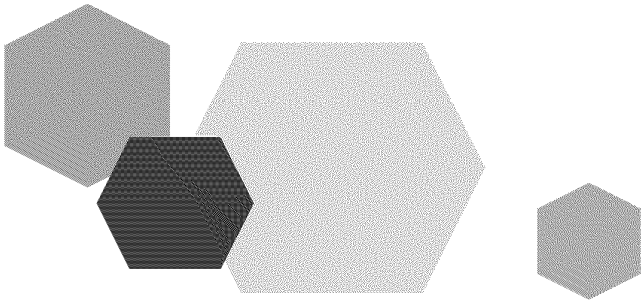
A new resource addressing the needs of parents and families by providing balanced and scientifically accurate health information on chemical hazards and safe use of chemicals around children.

Partnerships:

Superfund Research Program, Harvard University

Drug and Poison Information Center (DPIC)

Training



Workshops, Courses, and Webinars. Off-the-shelf or Customized

Dose-Response Assessment Boot Camp continues to be our most popular course. Our original 5-day course which is an intensive hands-on training in hazard characterization and dose-response assessment.

Boot Camp Basics begins with an introduction to toxicology for risk assessors. It addresses the fundamental approaches used in hazard characterization and dose-response assessment, as well as introducing complex concepts and modeling.

Boot Camp Advanced Framework and Modeling provides applications of advanced concepts and models, including mode of a provides applications of advanced concepts and models, including mode of action evaluation techniques, use of dosimetry and PBPK models, benchmark dose modeling, structure activity evaluation tools and methods, systems biology and other tools essential to the advanced risk assessment practice.

Practitioner's Guide to Development & Reproductive Toxicology (DART) A 4 hour webinar intended for health scientists and product stewardship professionals, addressing key issues for understanding and interpreting reproductive and developmental toxicity assays, as well as how such data are interpreted in a risk assessment context.

Non-Cancer and Cancer Risk Assessment A 6 hour course providing key concepts of non-cancer and cancer risk assessment followed by a detailed discussion of the methods for hazard characterization and dose-response.

Dosimetric Adjustments in Dose-Response Assessment A 4 hour course designed to provide basic training in dosimetric adjustments for oral and inhalation exposures in dose-response assessment.

Use of Chemical Specific Adjustment Factors A 6 hour course teaching participants methods for refining interspecies and intraspecies uncertainty factors based on toxicokinetic or toxicodynamic data, using chemical-specific adjustment factors (CSAFs)/ data-derived extrapolation factors (DDEFs).

Benchmark Dose Modeling An 8 hour course designed to give an overview of benchmark modeling software for cancer and non-cancer dose-response assessment. This course also provides hands-on experience in using the EPA BMDS software.

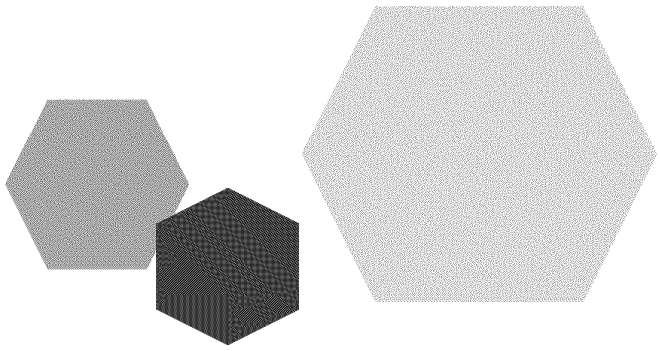
Children's Risk Issues A 1.5 day course discussing the major issues relating to risk assessment for children, such as toxicokinetic differences between adults and children, consideration of windows of susceptibility, and adequacy of the database uncertainty factor.

Mixtures A 2 day course helping scientists to understand and apply methods for risk assessment for multiple exposures or multiple routes ("mixtures risk assessment" or "combined exposures" or "cumulative and aggregate exposure"). Topics include additivity approaches, consideration of interactions, and strategies for addressing complex exposures scenarios.

Occupational Exposures Limit (OEL) Course A 4 day course similar to the Dose-Response Assessment Boot Camp, but focuses on the development of occupational exposure limits (OELs). The training covers the development of OELs, appropriate safety factors, exposure assessment, and hands-on activities to engage all participants.

Globally Harmonized System (GHS) Training A training tailored to corporate needs and circumstances. TERA provides firms with written certification as proof of meeting OSHA requirements. We are familiar with GHS as it relates to the Environmental, Health and Safety (EHS) needs and interests of private corporations and public agencies alike.

Emergency Management and Response Training A 3 day course touching on key toxicology and risk assessment concepts, with an in-depth focus on tools for preventing and responding to chemical emergencies including CAMEO, ALOHA, and MARPLOT. This course is offered onsite to members of your ERM team. CEU credits are available from the University of Cincinnati.



Risk Assessment Lecture Series

TERA is sponsoring a new monthly Risk Assessment Lecture Series within the Department of Environmental Health, University of Cincinnati. The lecture series will be on a range of "risk assessment" topics from a variety of risk assessment experts from various organizations and fields of study.

Dr. Charles Menzie, Global Executive Director for the Society of Environmental Toxicology and Chemistry (SETAC) and a principal with Exponent Inc., a science and engineering consulting company, was the inaugural speaker Friday, November 20th. He presented on "*Using Causal Analysis for Evaluating Environmental and Health Issues.*" Since then, topics covered have ranged from issues on hazard & dose response assessment, TOXCAST/TOX21, epidemiology-based risk assessment, and asthma. Speakers have volunteered from various organizations and agencies, such as National Institute of Occupational Safety and Health (NIOSH), U.S. Environmental Protection Agency (EPA), University of Cincinnati, and many others.

The Seminar series is held every third Friday of the month. Anyone outside of the Cincinnati area can participate via webinar. Details on the seminars and how to register can be found on the website at http://eh.uc.edu/tera/seminars/

Posters & Presentations

Sunday, 12:00 PM - 1:00 PM, Marriott Marquis Miramar Room: Alliance for Risk Assessment - "Beyond Science and Decisions"	
"Beyond Science and Decisions": Update and new developments	**L. Haber and M. Dourson**, Toxicology Excellence for Risk Assessment, Cincinnati, OH
Monday, 9:30 AM to 12:30 PM, CC Exhibit Hall: Poster Session: Risk Assessment I (J. Patterson, Chair)	
MCHM Spill in the Elk River—Toxicology and Risk Assessment. (#219)	**J. Patterson**[1], **M. L. Dourson**[1], J. Rosen[2], and A. Whelton[3]. [1]Toxicology Excellence for Risk Assessment, Cincinnati, OH; [2]Corona Environmental Consulting, Boston, MA and [3]Purdue University, West Lafayette, IN.
Mode of Action and Meta-Regression Analysis of the Effect of Trans Fatty Acids (TFAs) on LDL-Cholesterol (#224)	**L. T. Haber**[1], **J. F. Reichard**[1], **M. J. Vincent**[1], B. C. Allen[2], Liska, D.J.[3] and **M. L. Dourson**[1]. [1]Toxicology Excellence for Risk Assessment, Cincinnati, OH; and [2]BCA Associates, Chapel Hill, NC., [3]Biofortis
Monday, 12:15 PM -1:30 PM, Marriott Marquis, Del Mar Room: Turning Big Data to Knowledge (BD2K) Session	
Data Science and 21st Century Toxicology (12:15 PM)	**J. Reichard**, Toxicology Excellence for Risk Assessment, Cincinnati, OH
Monday, 1:00 PM to 4:30 PM, CC Exhibit Hall: Poster Session: Genetic Toxicology I	
Evaluation of cII Mutations in Lungs of Male Big Blue Mice Exposed to Vanadium Pentoxide by Inhalation for Up to 8 Weeks (#521)	M. G. Manjanatha[1], S. D. Shelton[1], **L. T. Haber**[2], B. Gollapudi[3], and M. M. Moore[1,4]. [1]Genetic and Molecular Toxicology, FDA/NCTR, Jefferson, AR; [2]Toxicology Excellence for Risk Assessment, Cincinnati, OH; [3]Center for Toxicology and Mechanistic Biology, Exponent Inc., Midland, MI; and [4]ENVIRON International Corporation, Little Rock, AR.
Quantification of Kras Codon 12 Mutations in Lung DNA of B6C3F1 Mice following Inhalation of Aerosolized Particulate Vanadium Pentoxide (#522)	M. Banda[1], K. L. McKim[1], **L. T. Haber**[2], J. A. MacGregor[1], B. Gollapudi[3], and B. L. Parsons[1]. [1]Division of Genetic and Molecular Toxicology, National Center for Toxicological Research, US FDA, Jefferson, AR; [2]Toxicology Excellence for Risk Assessment, Cincinnati, OH; [3]Toxicology Consulting Services, Arnold, MD; and [4]Exponent, Chicago, IL.
Monday, 3:15-4:15, Room 24A: Chemical Risk Assessment Best Practices Session	
Risk assessment databases: dissemination & communication of findings & risk values	**M. Dourson, P. Nance, O. Kroner**, Toxicology Excellence for Risk Assessment, Cincinnati, OH
Tuesday, 9:00 AM to 11:45 AM, CC Ballroom 6E: Workshop Session: Understanding and Communicating Uncertainty in Hazard Assessment and Dose Response	
Unpacking Toxicity Assessments to Understand and Improve Confidence (#873; 9:34AM)	R. L. Grant[1], S. L. Santos[2], **M. L. Dourson**[3], S. Shirley[4], N. K. Erraguntla[5], R. J. Lewis[5], and N. B. Beck[1]. [1]Regulatory and Technical Affairs, American Chemistry Council, Washington, DC; [2]Texas Commission on Environmental Quality, Austin, TX; [3]FOCUS GROUP Risk Communication and Environmental Management Consultants, Medford, MA; [4]Toxicology Excellence for Risk Assessment (TERA), Cincinnati, OH; and [5]ExxonMobil Biomedical Sciences, Inc, Annandale, NJ.
Presenting Uncertainty in the Context of Biological Monitoring and Exposure Information (#874; 10:03AM)	W. H. Farland[1], N. B. Beck[2], J. S. LaKind[3], **P. Nance**[4], and T. Simon[5]. [1]Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, CO; [2]Regulatory and Technical Affairs, American Chemistry Council, Washington, DC; [3]LaKind Associates, Catonsville, MD; [4]Toxicology Excellence for Risk Assessment, Cincinnati, OH; and [5]Ted Simon, LLC, Winston, GA.
Tuesday, 4:30 PM – 6:30 PM, Hard Rock Hotel, Satisfaction Room, OTR Planning Meeting	
Occupational Toxicology Roundtable (OTR) Planning Meeting	**R. Sandhu**[1], **P. Nance**[1], A. Adler[2], R. Sussman[2]. [1]Toxicology Excellence for Risk Assessment, Cincinnati, OH; [2]Safebridge Consultants, Inc., New York/California
Wednesday, 1:00 PM to 4:30 PM, CC Exhibit Hall: Poster Session: Bioinformatics	
Big Data to Knowledge (BD2K)—A Graphical Approach for Data Coordination and Integration (#2199)	**J. F. Reichard**[1], M. Medvedovic[2], and S. Sivagas[1]. [1]Toxicology Excellence for Risk Assessment (TERA), Cincinnati, OH; and [2]Department of Environmental Health, University of Cincinnati, Cincinnati, OH.
Thursday 8:30 AM –12:00 PM, Sails Pavilion: Late-Breaking Poster Session 4: Developmental Basis of Adult Disease and Developmental Toxicology	
Developmental Toxicity of Ethanol as a Topical Antiseptic in an Occupational Setting: A Review (#2675)	R. York[1], **B. Gadagbui**[2], A. Maier[2], A. Quiñones-Rivera[3]. [1]RG York and Associates, Manlius, NY; [2]Toxicology Excellence For Risk Assessment, Cincinnati, OH, University Cincinnati College of Medicine, Cincinnati, OH; [3]GOJO Industries, Inc., Akron, OH.

Presented at the 2015 SOT Annual Meeting

Presented at the 2015 SRA Annual Meeting

Session	Day	Paper#	Room	Author(s)	Title
WK45/11S	Sunday 8:30-5:30PM	Workshop		Haber; Musso	Fundamentals of the Risk Assessment Paradigm, From Hazard Characterization to Risk Communication, with an Emphasis on Contaminated Sites
M3-A	Monday	M3-A	A	Haber, Chair	D3: Doing Dose- Response Differently
	Monday	M3-A.1	A	Haber; Reichard; Vincent; Allen; Liska; Dourson	Mode of action and meta-regression analysis of the effect of trans fatty acids (TFAs) on LDL-cholesterol
P	Monday	P.27		Lange; Tao; Rhomberg; Goodman; Dourson; Honeycutt	Dose response curves derived from clinical ozone exposures can inform public policy
P	Monday	P.118		Willis; Ovesen; Reichard; Sandhu; Maier	Using pharmacokinetic data to replace default adjustment factors in assessing risk from non-clinical exposures to pharmaceuticals
P	Monday	P.189		Kroner; Haber; Dourson	The Dose-Response Framework: An online compendium of risk methods organized by problem formulation
P	Monday	P. 207		Nance, Dourson	Alliance for Risk Assessment Project: 1,4-Dioxane Reanalysis in Support of a Regenerative Hyperplasia Mode of Action (MOA)
T3-A	Tuesday	T3-A.3	A	Willis; Ovesen; Reichard; Sandhu; Maier	How does setting an Acceptable Daily Exposure (ADE) for pharmaceutical risk assessment differ from the U.S. EPA Reference Dose (RfD) approach?
W1-A	Wednesday	W1-A.2	A	Deveau; Maier; Meek; Krewski	Incorporation of chemical-specific data in dose–response assessments for occupational and environmental exposure limits
W4-D	Wednesday	W4-D.3	DE	Patterson; Kroner; Lee; Willis	A Tiered Approach to Investigate Metal Contamination in Unfinished Natural Materials Used in Children's Products
WK15T	Thursday 8:30AM-12:00PM	Workshop		Haber	Developments in Risk Assessment: State of the Science for Evaluating Toxicity Data for Human Health Risk Assessment

Special Issue Articles

- State-of-the-Science: The Evolution of Occupational Exposure Limit Derivation and Application
- Historical Context and Recent Advances in Exposure-Response Estimation for Deriving Occupational Exposure Limits
- Advances in Inhalation Dosimetry Models and Methods for Occupational Risk Assessment and Exposure Limit Derivation
- Systems Biology and Biomarkers of Early Effects for Occupational Exposure Limit Setting
- The Scientific Basis of Uncertainty Factors Used in Setting Occupational Exposure Limits
- Considerations for using Genetic and Epigenetic Information in Occupational Health Risk Assessment and Standard Setting
- Setting Occupational Exposure Limits for Chemical Allergens—Understanding the Challenges
- Exposure Estimation and Interpretation of Occupational Risk: Enhanced Information for the Occupational Risk Manager
- Aggregate Exposure and Cumulative Risk Assessment—Integrating Occupational and Non-occupational Risk Factors
- The Global Landscape of Occupational Exposure Limits—Implementation of Harmonization Principles to Guide Limit Selection

Publications

Allen, B.C., **M.K. Vincent**, D. Liska, and **L.T. Haber**. Meta-regression analysis of the effect of *trans* fatty acids on LDL-C. Accepted with minor revisions.

Banda, M., K.L. McKim, **L.T. Haber**, J.A. MacGregor, B.B. Gollapudi, and B.L. Parsons 2015. Quantification of *Kras* mutant fraction in the lung DNA of mice exposed to aerosolized particulate vanadium pentoxide by inhalation. Mutat Res Genet Toxicol Environ Mutagen. 789-790:53-60

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Greenberg M, Goldstein BD, Anderson E, **Dourson M**, Landis W, North DW. 2015. Whither Risk Assessment: New Challenges and Opportunities a Third of a Century After the Red Book. Risk Anal. 35 (11):1959-1968.

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Maier A, Vincent MJ, Parker A, Gadagbui BK, Jayjock M. 2015. A tiered asthma hazard characterization and exposure assessment approach for evaluation of consumer product ingredients. Regul Toxicol Pharmacol. doi: 10.1016/j.yrtph.2015.09.028. [Epub ahead of print]

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Manjanatha, M.G., S. D. Shelton, Y. Chen, B.L. Parsons, M.B. Myers, B.B. Gollapudi, N.P. Moore, **L.T. Haber**, B.C. Allen, and M.M. Moore. Ethylene oxide is a weak mutagen at the *cII* locus as evaluated in the lung of male Big Blue mice exposed for up to 12 weeks by inhalation. Accepted with revisions.

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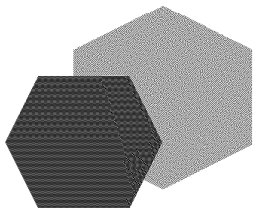
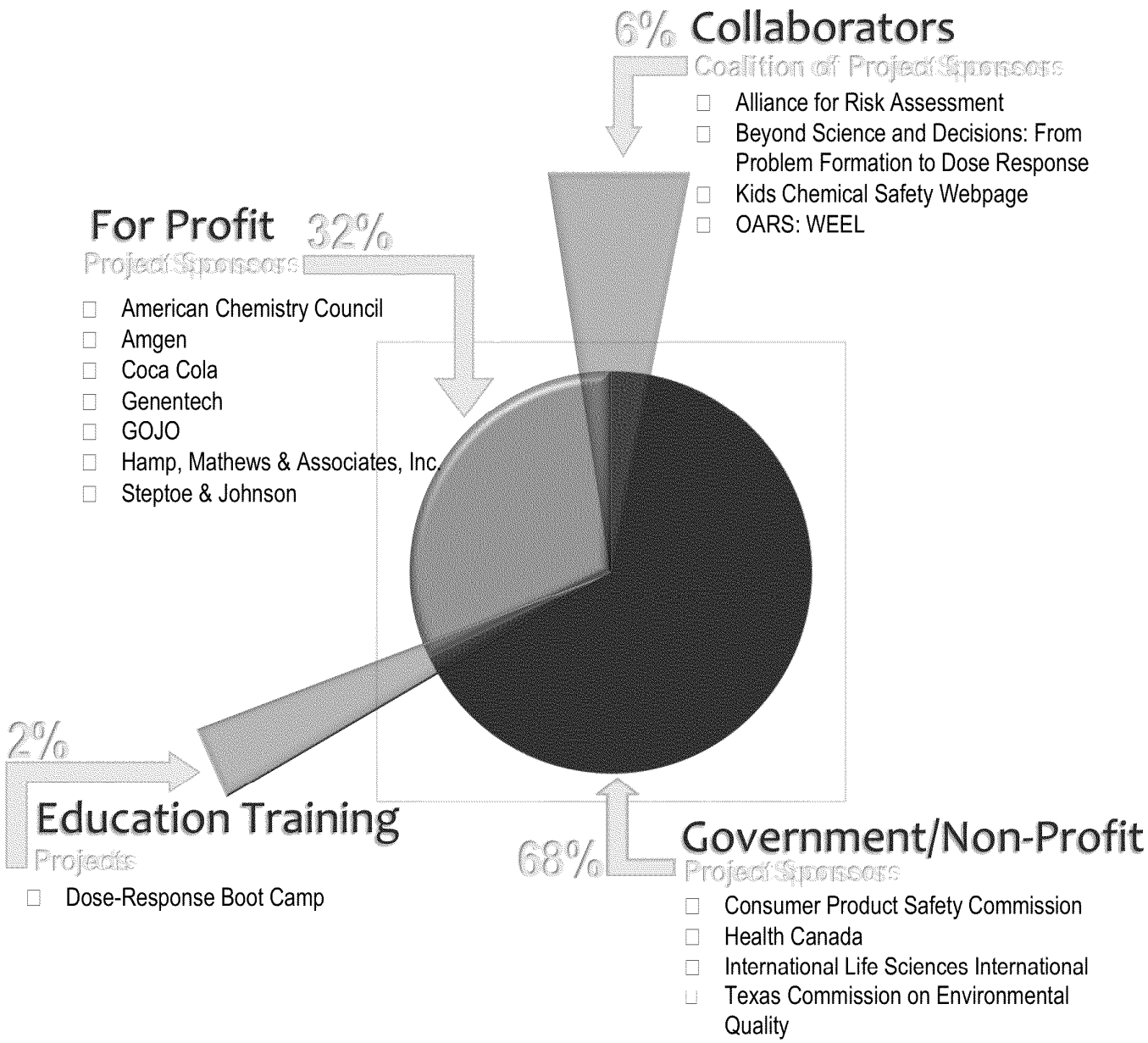
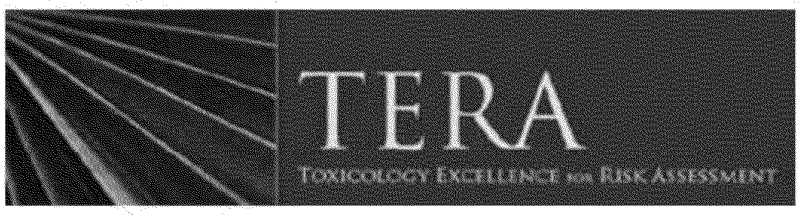


2015 TERA Project Time by Sponsor



The sponsors listed above are sponsors that each comprise 2% or more of our work.



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To: Lyons, Troy[lyons.troy@epa.gov]
Cc: Patterson, Jacqueline (patteji)[PATTEJI@ucmail.uc.edu]; Pat McGinnis[mcginnis@tera.org]; Maier, Michael (maierma)[maierma@ucmail.uc.edu]
From: Dourson, Michael (doursoml)
Sent: Fri 9/29/2017 12:49:38 PM
Subject: Addressing misinformation about TERA
Excerpts of TERA's Collaborative Work 9-28-17.docx

Troy

Ex. 5 - Deliberative Process

Cheers!

Michael

-- *Risk Science Center (formerly TERA Center)*
Integrating assessments for both human and environmental health. See
http://www.tera.org/EcoTERA/index.html

To: Palich, Christian[palich.christian@epa.gov]
Cc: Ringel, Aaron[ringel.aaron@epa.gov]; Lyons, Troy[lyons.troy@epa.gov]; Shimmin, Kaitlyn[shimmin.kaitlyn@epa.gov]; Frye, Tony (Robert)[frye.robert@epa.gov]; Rodrick, Christian[rodrick.christian@epa.gov]; Cory, Preston (Katherine)[Cory.Preston@epa.gov]; wwehrum@hunton.com[wwehrum@hunton.com]; Leopold, Matthew Z.[MLeopold@carltonfields.com]; David Ross **Ex. 6 - Personal Privacy**
From: Dourson, Michael (doursoml)
Sent: Mon 10/9/2017 1:48:51 PM
Subject: Re: QFR's
Dourson ALL QFR's 10.04.2017.docx
Attachment 2.docx
Attachment 1.docx
Corrected Question 3-Project Database January 2010 to June 2015.xls

Christian

Here are my draft answers. Please feel free to suggest modifications. I have no doubt that your team can improve these initial thoughts.

Cheers!

Michael

-- *If you can't explain it simply, you don't understand it well enough. Albert Einstein*

Risk Science Center
Department of Environmental Health

From: "Palich, Christian" <palich.christian@epa.gov>
Date: Friday, October 6, 2017 at 11:21 AM
To: "wwehrum@hunton.com" <wwehrum@hunton.com>, "Leopold, Matthew Z." <MLeopold@carltonfields.com>, Michael Dourson <doursoml@ucmail.uc.edu>, David Ross **Ex. 6 - Personal Privacy**
Cc: "Ringel, Aaron" <ringel.aaron@epa.gov>, "Lyons, Troy" <lyons.troy@epa.gov>, "Shimmin, Kaitlyn" <shimmin.kaitlyn@epa.gov>, "Frye, Tony (Robert)" <frye.robert@epa.gov>, "Rodrick, Christian" <rodrick.christian@epa.gov>, "Cory, Preston (Katherine)" <Cory.Preston@epa.gov>
Subject: QFR's

Hi All,

I had a call with Senate EPW this morning and protocol will be them emailing you directly (CCing us of course) your final QFR's. The due date for Senate offices to submit to EPW is a hard deadline of **4:30pm today**, and you should receive them no later than **6pm this evening** to begin working on them. Please remember we will need completed drafts by no later than **noon Monday.**

Just wanted everyone to have a clear timeline for the day.

Thanks and please let me know if you have any questions.

Christian R. Palich

Deputy Associate Administrator

Office of Congressional & Intergovernmental Affairs

U.S Environmental Protection Agency

O: 202.564.4944

C: Ex. 6 - Personal Privacy

E: Palich.Christian@epa.gov